EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Wave 8 Cases*	

GENERAL EXPERT REPORT OF PETER K. SAND, M.D.

TVT Expert Report of Peter K. Sand, M.D.

My name is Peter K. Sand and I currently reside in Winnetka, Illinois. I am currently licensed as a medical doctor in the state of Illinois (since 1980) and practice in the field of Obstetrics & Gynecology at NorthShore University HealthSystem in Skokie, Illinois. My special clinical and academic interests are in female pelvic medicine and pelvic reconstructive surgery, including minimally invasive treatment for urinary incontinence, pelvic organ prolapse, benign vulvar disease, and chronic pelvic pain.

A. Qualifications, Education, Training, Background and Experience

I have been a medical doctor for 38 years and am Board Certified by the American Board of Obstetrics & Gynecology with a Subspecialty Board Certification in Female Pelvic Medicine and Reconstructive Surgery. As a board-certified Urogynecologist/Pelvic Surgeon, this subspecialty discipline has defined my practice for the past 34 years.

I received my medical degree in 1980 from Northwestern University Medical School. I then went on to complete my Internship and Residency at Prentice Woman's Hospital of the Northwestern University Medical School in Obstetrics and Gynecology (1984). I completed a two year fellowship in Gynecological Urology and Pelvic Surgery at Memorial Medical Center in Long Beach and the University of California, Irvine in 1986.

I completed my General OB-GYN Board Certification in 1988. Since 1984, I have exclusively practiced and taught urogynecology and pelvic surgery, becoming board certified in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery by the American Board of Obstetrics and Gynecology the first year that certification became available (2013).

I am currently a Clinical Professor of Obstetrics and Gynecology at the University of Chicago, Pritzker School of Medicine. I also serve as the Director of urogynecology research for the Division of Urogynecology in the Department of Obstetrics and Gynecology, NorthShore University HealthSystem. I have founded two Divisions of Urogynecology and two Fellowship Programs in Female Pelvic Medicine and Reconstructive Surgery.

I have held various faculty appointments, including the Clinical Instructor, Department of Obstetrics and Gynecology, University of California, Irvine, 1984-1986; Assistant Professor, Department of Obstetrics and Gynecology, Rush Medical College, 1986-1991; Associate Professor, Department of

Obstetrics and Gynecology, Northwestern University Medical School, 1991-2002; Professor, Department of Obstetrics and Gynecology, Northwestern University Medical School, 2002-2009; and Clinical Professor, Department of Obstetrics & Gynecology, University of Chicago, Pritzker School of Medicine, 2009- present.

I have held various administrative appointments, including the Director, Section of Urogynecology, Rush Medical College, 1986-1991; Director, Rush Urodynamics Center, Rush Medical College, 1986-1991; Assistant Director of Residency Education, Department of Obstetrics and Gynecology, Rush Medical College, 1986-1988; Director, Rush Laser Center, Rush Medical College, 1987-1991; Director, Fellowship in Urogynecology, Rush Medical College, 1987-1991; Director, Division of Urogynecology, NorthShore University HealthSystem, 1991-2010; Director, Evanston Continence Center, NorthShore University HealthSystem, 1991-present; and Director, Fellowship in Urogynecology and Reconstructive Pelvic Surgery, NorthShore University HealthSystem, 1992-2011.

I am a member of the American Congress of Obstetrics and Gynecology (1980-present), American Urogynecology Society (1984-present), International Continence Society (1985-present), and the International Urogynecological Association (1985-present). I have served in several leadership and committee positions over my career in the preeminent professional organizations whose mission is to care for women's pelvic disorders, including as serving as the President of the International Urogynecological Association and President of the Foundation for International Urogynecological Assistance.

I have been the recipient of various awards for both academic and clinical work, including the First Annual Ralph Reis Research Award (1981), The Purdue-Frederick Award (1983), the Fourth Annual Ralph Reis Research Award (1984), Evanston Hospital Research Award (1984), Central Prize Award of the Central Association of Obstetricians and Gynecologists (1985), Illinois Award (1987 & 1989), Award for Research by the Society of Obstetricians and Gynecologists of Canada (1989), Organon Ovestin Award (1993), President's Award by the Society of Gynecologic Surgeons (2001), ACOG/Pharmacia Corporation Research Award (2002), Young Investigators Award of the Central Association of Obstetricians and Gynecologists (2002), International Health Professional of the Year (2005) and Roy Pitkin Award for Excellence in Research (2006).

I have served as the editor, reviewer and consultant on various publications in numerous journals pertinent to female pelvic health and surgery such as the American Journal of Obstetrics and Gynecology,

International Urogynecology Journal, Obstetrics and Gynecology, International Journal of Gynecology and Obstetrics, Neurourology and Urodynamics, Urology, Journal of Urology, Journal of Pelvic Surgery, Therapy, the British and European Journals of Obstetrics & Gynecology, the British Journal of Urology International, Journal of Sexual Medicine, Hospital Practice, and the Expert Review of Obstetrics & Gynecology.

I have published over 230 papers in peer-reviewed journals and over 25 book chapters on the topics of obstetrics, gynecology, urogynecology and reconstructive surgery. For over 30 years I have regularly attended scientific, annual and other meetings of the various professional societies pertinent to female pelvic health such as the International Urogynecological Association (IUGA), International Continence Society (ICS), American College of Obstetricians and Gynecologists (ACOG), American Urogynecologic Society (AUGS), American Urological Association (AUA), Society of Gynecologic Surgeons (SGS), American Association of Gynecologic Laparoscopists (AAGL), Sexual Medicine Society of North America, and the Society for Urodynamics and Female Urology (SUFU), and have presented study data to attendees. I have obtained grants for over 40 research projects and have served as a Principal Investigator in numerous randomized controlled trials pertinent to pelvic surgery and/or the treatment of conditions within the spectrum of female pelvic health.

I have taught medical students, residents and fellows for decades and am familiar with national standards, knowledge and practice expectations, and educational training curriculum. Beginning in 1985, I developed a teaching curriculum for junior and senior medical students in the Ambulatory Urogynecology Clinic, Memorial Medical Center of Long Beach, University of California, Irvine. In 1988, I was involved in developing Guidelines for Resident Education in Urogynecology, in connection with my role as a member of the American Urogynecologic Society's Education Committee. Also in 1998, I developed a Cadaveric Instructional Hands-on Laboratory in Pelvic Anatomy for Residents in Obstetrics and Gynecology at Rush Medical College. From 1988 to 1991, I started the Fellowship program in Urogynecology at Rush. In 1992, I then started a second Fellowship in Urogynecology and Reconstructive Pelvic Surgery at Evanston Northwestern Healthcare, Northwestern University Medical School. I helped develop the Educational Guidelines for Medical Student, Resident and Fellow Education (Core Curriculum) in Urogynecology and Reconstructive Pelvic Surgery for the International Urogynecological Association. I have developed and started numerous post-graduate courses pertaining to Urogynecology and Reconstructive Pelvic Surgery, Urodynamics, and Gynecologic Urology. In these roles I

have taught students, residents, fellows and practicing gynecologists about pelvic floor disorders, their treatment including surgery and the different types of surgical options, as well as the potential risks and benefits of pelvic surgery, the expected knowledge and competency of the practicing pelvic surgeon, how to counsel patients on their condition and the potential risks and benefits of treatment including surgery, evidence-based pelvic medicine, and post-operative care. I am knowledgeable with residency and fellowship requirements that pertain to the training of pelvic surgeons and that the use of midurethral slings including TVT are part of the core competencies of our national curriculum as well as the board certification process.

I have taught and performed different types of mesh and non-mesh stress urinary incontinence and pelvic organ prolapse surgeries. I have published on operative technique and outcomes in various cohorts. I have used both retropubic and transobturator midurethral slings as well as hand cut mesh for pelvic surgeries. I have utilized a wide variety of biomaterials in surgery and followed patients after surgery. I estimate that I have performed over 500 surgeries utilizing the Ethicon TVT retropubic device.

For further information, please see my attached Curriculum Vitae (CV).

B. <u>Fees, Testimonial History and Materials Reviewed</u>

My fees for expert review are $600 per hour for review and $750 per hour for deposition and trial testimony with a half day minimum for trial testimony. In the past four years, I have given expert testimony in the following cases: Govea v. Feinstein (Court #11L566), Schmalz v. Northwestern Memorial (Court #2011L5175), Cooley v. Menchaca (Court #12L9548), Rosetti v. Edward Hospital (Court #10L006955) and Kurtis v. Mueller.

I have reviewed the medical literature and Ethicon materials such as the Ethicon TVT Instructions for Use, TVT Surgeons Resource Monograph, and the Professional Education materials made available to the intended user. These materials are included in my Materials List, which is attached to this report, and/or mentioned in this report. I reserve the right to utilize these materials as exhibits at trial, as well as the materials and studies as set forth in my CV. I have also reviewed the TVT reports and materials cited by Plaintiffs' experts such as Bruce Rosenzweig, MD and Jerry Blaivas, MD.

Below are my opinions in this case as of the date of this report. To the extent I receive additional information between now and the time of the trial, my opinions may be modified, I may form additional opinions and I

may issue a supplement to this report. My opinions are held to a reasonable degree of medical and scientific certainty and probability and are based on my education, training, medical knowledge, clinical experience, the medical literature and materials that I have reviewed, my research, my professional activities and attendance at congresses, and my leadership and editorial roles pertinent to female pelvic medicine.

C. Stress Urinary Incontinence and TVT

During the course of my over 30 years of practice, I have treated female patients for a variety of health care related issues. Within the field of Obstetrics & Gynecology, one of the most frequent health problems that I see involves a female patient who suffers from urinary incontinence.

There are numerous types of urinary incontinence symptoms, but the two most common are urgency and stress urinary incontinence. Urgency urinary incontinence (UUI) is a condition where there may be sensory and motor changes that result in increased urinary urgency with the development of frequent urination often accompanied by urinary incontinence. Stress urinary incontinence (SUI) occurs when a woman increases her abdominal pressure such as when she coughs, exercises, or performs some movement of the body that increases the abdominal pressure exerted on the bladder. This pressure, due to certain anatomical issues, causes leakage of urine that is involuntary and outside of the control of the woman. When these two types of urinary incontinence coexist, it is referred to as mixed urinary incontinence or MUI. MUI is also common as coexistent detrusor overactivity (DO) and UUI have been reported to occur in up to 50% of patients with SUI. The number of women with urinary incontinence has been increasing over the past decades and is projected to increase 55% from 18.3 million to 28.4 million from 2010 to 2050 with an aging population.[i] As can be imagined, urinary incontinence causes loss of bladder control and significantly impacts a woman's social and sexual life, and also her general quality of life.[ii] As discussed later, against this backdrop, the desirability and need for a minimally invasive, effective surgical option to treat SUI became needed within the field, and TVT fulfilled this role.

For the next section, I am only going to focus on SUI. From an anatomical standpoint, SUI focuses on the bladder and the urethra. The bladder is the organ that holds the urine and the urethra is the tube through which the urine is transported from the bladder to the urethral meatus or opening for elimination by the body. With aging and childbirth, the muscles and connective tissues (pelvic floor) which support the bladder and urethra can become damaged. Without adequate support of the pelvic floor

muscles, more abdominal pressure is transmitted to the bladder than the urethra and that results in a gradient which can lead to the bladder pressure exceeding the urethral pressure and urine leaking out through the urethral meatus. This process becomes more likely with aging because of decreases in voluntary and involuntary muscle strength in the urethra with aging. Whenever the bladder pressure exceeds the urethral pressure, urine will leak out through the urethra and out of the body.

When a female patient has symptoms of SUI, examination and testing are typically performed to make a formal diagnosis of the underlying etiology of this symptom. In addition to taking a medical history and performing a physical examination, tests are available where fluid is inserted into the bladder under pressure to test when and if leakage occurs. There are varying degrees of SUI and treatment recommendations may vary from one patient to another. A diagnosis of SUI is not uncommon in females and it is estimated that over 13 million women are impacted by this condition (just in the United States alone).

When it comes to treatment of SUI, there are surgical and non-surgical options that are available. The non-surgical options involve exercises (such as Kegel's) which are focused on teaching women to specifically work the pelvic floor muscles with the hope of strengthening them. Other pelvic floor muscle training can include biofeedback, vaginal cones and pelvic floor physical therapy. Pelvic floor electrical stimulation may also be used to strengthen the urethral and periurethral musculature. Intravaginal support devices and even obstructive or occlusive urethral devices may be used to treat SUI. In contrast to UUI, current medications for SUI are not FDA approved and have poor therapeutic indices (their side effects outweigh their benefits).

Conservative treatment does not always work (and is not always required) and surgical treatment may be used as a first line of therapy in the appropriate clinical circumstances. Labrie et al published a randomized controlled trial (Level I evidence) in the New England Journal of Medicine that showed that women with moderate-to-severe stress urinary incontinence had significantly better subjective and objective outcomes at 12 months after surgery with the Ethicon TVT device than after physiotherapy.[iii]

For surgical options, the surgical approach for treatment of SUI has evolved with the advancement of medicine, however, the concept is the same. The surgical treatment focuses on providing support for the urethra to promote equal transmission of abdominal pressure to the urethra compared to the bladder. This has been accomplished by surgically

entering the area and through the use of sutures and different materials, such as the Prolene polypropylene sling utilized in the TVT device, supporting the tissues under the urethra or creating "slings" that lift and support the urethra. The sutures and "slings" were typically attached to tissue or bone within the pelvis to provide an anchor for the materials, although with the advent of the TVT device and its unique tension free design, direct fixation, anchoring and suture bridging was not needed. This reduced the risks and complications associated with increased dissection, bigger incisions and sometimes increased urethral compression with these older procedures. Marshall Marchetti Kranz procedures, Burch procedures and autologous or biologic pubovaginal or bladder neck slings took longer to perform and were associated with more complications than the TVT.

One of the early procedures, still performed today but typically only in very limited circumstances, is known as the Burch procedure. This was first described in 1961.[iv] One of the downsides of the Burch procedure, while it was a very popular procedure for SUI, is that it involves open abdominal surgery and generally an inpatient stay at the hospital.

Sling procedures date back to 1907. These operations were first applied at the bladder neck. The surgeon would harvest fascial tissue from the patient or from a cadaver, and use this human tissue to make a sling that would lift the bladder neck. With the sling at the bladder neck, there was a high risk of obstruction of the bladder neck and therefore increased voiding dysfunction including incomplete bladder emptying and increased urgency and UUI postoperatively, as well as the additional morbidity and wound complications that arise from the need to harvest fascia with autologous slings.[v]

Other procedures such as the anterior (Kelly plication) repair and needle suspension procedures (Pereya, Raz, etc.) were historically used by some surgeons. While the needle suspension procedures encompassed an arguably less invasive design than the MMK, Burch, and pubovaginal slings, these were shown to be significantly less efficacious- the more they were studied. The anterior repair was also shown to be a poor choice for treating SUI with poor long term success. Since the employment of the modern TVT sling design, with its less invasive placement, standardized technique, low morbidity, short convalescence, and proven efficacy and safety in the short, medium and long term (as later discussed), these surgeries have fallen out of routine use and are not recommended by the gynecologic, urologic and female pelvic medicine medical societies. They are historical notes in the pertinent textbooks of the pelvic surgeon such as those to which I have contributed and are infrequently performed

or taught- nor are they expected to be within the repertoire of future pelvic surgeons.

One of the problems with using human or living tissue during the repairs for SUI is that the tissues can degrade over time and there can be pain at the harvest site. Slings were revolutionized by Ulmsten and Petros who described the first midurethral sling in the mid 1990's utilizing a synthetic sling.[vi] A sling could be made out of the mesh, cut to any size that was needed, and then was placed under the midurethra to support it. Due to the location of this sling, it is commonly referred to as a "midurethral sling" (MUS). Different materials were tested over many years and in the end, a loosely knitted Prolene polypropylene mesh material was chosen due to its beneficial tolerability, biocompatibility, efficacy and safety profile.[vii] The location of this sling has the benefit of helping to support the urethra and being highly effective at stopping leakage, while also having a lower risk than the Burch procedure and the autologous sling in causing voiding issues such as voiding dysfunction, obstruction and retention following the procedure.[viii]

The midurethral sling is the best approach for addressing SUI surgically and this has consistently been stated by the medical community. In February 2018, the Society for Urodynamics and Female Urology and the American Urogynecologic Society et al, stated that "the polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence" and further that "the procedure is safe, effective, and has improved the quality of life for millions of women."[ix]

There is substantial research supporting this position. Following the launch of TVT, it was studied in numerous types of patients who had SUI, including primary SUI, those with intrinsic sphincteric deficiency (ISD), MUI, and recurrent SUI, and shown to be very efficacious and safe. These early data have been reproduced in the voluminous literature concerning TVT including systematic reviews and meta analyses.[x] There was desirability in the field for an option that could demonstrate effectiveness and safety across the numerous types of patients who present with burdensome SUI, and TVT met this need.

TVT has been the subject of numerous registries in large groups of patients and has shown high efficacy and low rates of serious complications including bladder perforation in 2.7% to 3.9% of cases, urinary retention in 1.6%, pelvic hematoma in 0.7% to 1.9%, infection in 0.7%, vaginal tape exposure in 1.5%, groin pain in 0.4%, and reoperation rates relating to tape insertion or postoperative voiding dysfunction have ranged from 1.6% to

2.4%.[xi] The TVT is the most studied anti-incontinence device and surgical option for treating SUI.

Well over 100 randomized, controlled trials and cohort studies for as long as 17 years support its use. The recent Cochrane Review by Ford et al. demonstrates that TVT has high levels of efficacy and a low rate of complications including a 1-2% exposure rate, improvement in voiding during intercourse and is the most studied surgical option.[xii] There are so many long term studies on the TVT device that a systematic review and meta analysis of these studies with a duration of ≥5 years was able to be performed by Tommaselli et al, who evaluated 3,974 retropubic MUS patients of which 3,801 received a TVT across 30 studies, and the results showed a 2% mesh exposure rate and only 13 patients (0.3%) had persistent or chronic pain (i.e. pain persisting beyond the perioperative period or reported at the last follow-up visit).[xiii] TVT has been studied out to 17 years, the most recent of which was reported by Braga et al, where TVT was shown to have sustained efficacy (89.1% subjective and 91.4% objective cure rates) and a very safe complication profile as the authors noted that no patients had significant pelvic organ prolapse, vaginal, bladder or urethral erosion, or de novo dyspareunia; and no patient required tape release or resection during the 17 year study.[xiv]

Other long term large datasets confirm the efficacy and safety of TVT. Svenningsen et al reported on a cohort of 483 TVT patients with a median follow up of 10 years and 9 months which showed an 89.9% objective cure rate, a 76.1% subjective cure rate, a 94.1% subjective improvement rate, an 82.6% treatment satisfaction rate, with a mesh exposure rate of 0.8%, a revision rate of 0.6% (3 of 4), and a 1.9% sling release rate.[xv]

Kurkijärvi et al. reported data on TVT and the Burch procedure in a Finnish registry of 38,500 women and the data demonstrated that TVT had a significantly lower reoperation rate than the Burch procedure (3% versus 14%, p<0.0001). In the sub-group of 22,549 women with 5 year follow-up, the rate of reoperation was again more common after a Burch procedure compared with the TVT device (OR 1.7, 95% CI: 1.5–2.0) or any MUS (OR 1.7, 95% CI: 1.5–1.9, p <0.0001). In the group with the longest follow-up, 10,689 women with 10 years follow-up, 9.3% of women had reoperation after a Burch procedure versus 6.1% after TVT and the odds of having a reoperation after a Burch procedure was again significantly higher than TVT (OR 1.6, 95% CI 1.3–1.9, p < 0.0001)).

Holdo et al showed that TVT had a significantly lower rate of recurrence than the Burch procedure.[xvi] They also showed that at 12 years TVT had significantly lower rate of repeat surgery for incontinence (11.0% Burch

(14/127) and 1.7% TVT (3/180; p < 0.001)) and prolapse (16.5% Burch (21/127) and 5.6% TVT (10/180; p = 0.01). Fusco et al's recent systematic review and meta analysis was consistent and showed that TVT/MUS patients had significantly higher overall (odds ratio [OR]: 0.59, p=0.0003) and objective (OR: 0.51, p=0.001) cure rates than Burch patients.[xvii]

The Society of Gynecologic Surgeons has researched the various surgical options and published its Level I review, metaanalysis, and practice recommendations.[xviii] All but 1 of the 19 RCTs that evaluated retropubic slings studied the TVT device and it was consistently supported by the largest efficacy and safety dataset available across all of the SUI surgeries evaluated. For example, Table 3 contains complication rates of the various options. Hematoma has the largest dataset with TVT being assessed across 25 different studies comprising 15,950 patients, with a rate of 0.88%. By comparison, even though they have been in existence longer, the Burch procedure was assessed in 4 studies of 542 patients with a hematoma rate of 1.4% and the pubovaginal sling was assessed across 5 studies including 677 patients with a hematoma rate of 2.2%.

Several other studies support the use and safety of TVT and MUS in hundreds of thousands of patients and these data show a low rate of reoperation at less than 4% out to 10 years. Jonsson Funk et. al. evaluated a cohort of 188,454 US women and reported a 9-year rate of urethrolysis or mesh removal of 3.7% (9 year risk of 2.5% for mesh erosion vs. 1.3% for urinary retention).[xix] Welk et al evaluated on a cohort of 59,887 women who had undergone MUS and reported that a cumulative incidence of 3.3% underwent treatment for complications.[xx] Nguyen et al evaluated a cohort of 4,142 patients from the Kaiser Permanente California and Hawaii database and reported that 1.2% underwent sling loosening or transection for retention, 0.9% underwent excision for mesh exposure, 0.08% underwent excision for urethral erosion, and 0.04% underwent excision for pain or drainage of a hematoma.[xxi] Unger et al evaluated a cohort of 3,307 patients and reported that 2.7% underwent sling revision.[xxii] Notably, these data are consistent with the rates of mesh revision (1-4%) noted in the TVT long term studies and TVT RCTs, as well as the Cochrane Reviews and the metaanalysis of TVT registries earlier discussed. There is significant desirability and utility in having large amounts of high level data from which to base practice

recommendations and patient counseling and outcomes and midurethral slings are hands down the Gold Standard of SUI surgeries.

Midurethral slings have received FDA clearance and broad acceptance in the medical community. As mentioned previously, I have performed many midurethral sling procedures including the TVT and the benefits of using these products far outweigh the risks. This is not to say that there are no risks from using these products- as there are risks with any surgical procedure. However, the risks for these products were and are well-known and documented by the medical community. While complications can occur with mesh slings, the same complications can occur with non-mesh slings. The complications with the various SUI surgeries have been reported by the medical community both before and after the release of TVT and are expected knowledge of the surgeon based on their education and training, their professional experience, participation in continuing medical education and conference attendance, the medical literature and the expected standard of care in my field.[xxiii]

Further, the TVT has an Instruction for Use (IFU) document that describes the recommended procedure to be used when implanting the device. The IFU includes contraindications, warnings and precautions and known complications and risks (adverse reactions) associated with the device considering the common knowledge of the pelvic surgeon. The IFU is not a replacement or substitute for the many years of education, training, and experience of the pelvic surgeon, nor is it written to replace the numerous textbooks that are required reading, and following the medical literature which is expected of the practicing pelvic surgeon, in order to understand the potential benefits and risks of pelvic surgery, using a mesh device, and to counsel patients. For example, the TVT IFU states: "It is not a comprehensive reference to surgical technique for correcting Stress Urinary Incontinence (SUI). The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the GYNECARE TVT device. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy." The IFU also warns that "Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT system before employing the GYNECARE TVT device." In addition, professional educational materials such as the TVT Surgeons' Resource Monograph, TVT slide decks and surgical videos, and other training materials are available for physician usage. These TVT materials are adequate for use by pelvic surgeons given their expected common knowledge and the literature. In addition, since the 2000s, the TVT has

been taught to both residents and fellows across the United States and has been deemed a part of the core curriculum for pelvic surgeons. Knowledge of its potential benefits and risks, as well as the risks of surgery, are a prerequisite for and expected subject of practicing gynecologists and urogynecologists and the ObGyn and FPMRS boards.

The fact remains that compared with the prior surgical options for the treatment of SUI, the TVT it is easily taught and performed, it is less invasive requiring less dissection and much smaller incisions, it has a shorter recovery time, does not require general anesthesia, has high levels of efficacy that are sustained over time as opposed to the Burch colposuspension, and it causes less surgical pain and overall fewer complications, which has led to its role as the Gold Standard and a recommended first line, suitable, safe and effective surgical option by the pertinent societies.[xxiv] As a result, it has been shown to be the preferred surgical option for treating SUI.[xxv]

TVT is made from Prolene polypropylene. Given the number of medical products that are acceptable for use within the human body that are comprised of polypropylene, the safety of mesh made from polypropylene is well documented and accepted within the medical community- as the data in my report clearly shows. As for degradation or cytotoxicity of polypropylene, I am not aware of any valid medical research or literature supporting this. I am aware of discrepant in vitro cell line testing that reported cytotoxicity, which was submitted to the FDA in the TVT 510k, but the other data and in particular the human clinical data showed no evidence of cytotoxicity. If the TVT mesh were cytotoxic, then it would not incorporate into the body. Instead there would be necrosis and the body would reject the TVT mesh in all cases. As discussed, the clinical data do not support this. Further, I have not experienced this in my clinical practice, nor have I experienced or seen any evidence of the mesh causing chronic systemic inflammation or degrading.

While some of Plaintiffs' experts have opined that TVT induces a harmful immunogenic, inflammatory and possibly malignant response in host tissues,[xxvi,xxvii] the data do not support these speculative opinions. They base these opinions on data in animal studies showing induction of sarcomas in mice with polypropylene coated transponder chips[xxviii] and sarcomas induced in rats that had radiated polypropylene discs implants.[xxix] But Witherspoon et al. showed no tumor induction in mice over two years who had monofilament polypropylene hernia mesh implanted.[xxx] The absence of tumorigenesis following implantation of a loosely woven polypropylene mesh in a rodent model is likely due to the "Oppenheimer effect". Oppenheimer showed that the surface

characteristics of an implant are important in tumorigenesis. They showed that while inert materials (glass and inert metals) implanted as discs and sheets might induce sarcomas whereas the powder and porous forms of these materials would not induce cancers in the same species. This would explain why smooth sheets and discs of polypropylene would induce sarcomas but polypropylene mesh would not. It is important to recognize that tumorigenesis in rodents is common and very rare in humans. Therefore, it is reckless to presume that just because an implant may be carcinogenic in rodents that this will be relevant in humans. Moalli and colleagues bring up the potential absurdity of directly translating animal research data to human clinical care in referencing the article by Moore and Palmer in 1977, reported in the Journal of the American Medical Association entitled "Money causes cancer: ban it".[xxxi] They found that implanting metal coins into rats caused 60% to develop sarcomas within 16 months.

In humans, it is important to understand that when a surgical incision is made and a dissection is carried out (such as in the placement of a midurethral sling) a normal cascade of events is triggered in mammalian tissues to respond to the injury. Initially, a cascade of hemostasis, inflammation, proliferation, and remodeling will occur over time with the generation of scar tissue.[xxxii] The quality of the scar tissue and its integration into the surrounding tissues will vary based on numerous host characteristics including the presence of pre-existing immunological disease, history of smoking, obesity and diabetes.

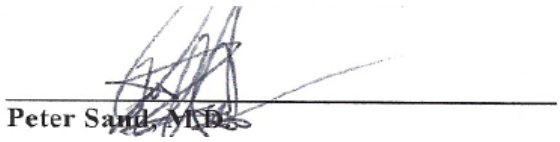
Chughtai et al have studied these issues in humans and have reported that the use of urogynecological mesh including slings is not a cause of an immunogenic response, the development of autoimmune disease[xxxiii] or carcinogenesis.[xxxiv] Other epidemiologic studies show no association between the use of polypropylene slings and cancer or sarcoma. For example, King et al[xxxv] specifically examined the malignant potential of polypropylene midurethral slings in a single center study of 2,361 such slings performed at their institution between 2004 and 2013 With an average follow-up of 42 months, and as long as 122 months, they noted that 2 of the 2,361 women had developed a single bladder and a vaginal cancer felt to be unrelated to the sling placement. The bladder cancer was a high grade urothelial cell carcinoma that occurred 4 years after a transobturator midurethral sling with no bladder perforation. The vaginal cancer was anatomically separate from the sling at the apex and was associated with human papilloma virus. The overall incidence of related tumorigenesis was 0%. Linder et al also examined a cohort of 2,474 patients who underwent polypropylene MUS at the Mayo Clinic. [xxxvi] The median age was 57 years and the median follow-up was 60 months.

Overall, 51 patients had a cancer diagnosis (8 bladder cancers, 7 vaginal malignancies, 8 ovarian carcinomas, 26 endometrial cancers, 2 cervical malignancies), but only 2 cancers (0.08 %, 2 out of 2,474) developed following sling placement (a vaginal melanoma 3 years after sling placement and an ovarian tumor 1 year after sling placement). No cases of sarcoma formation, bladder, urethral or squamous cell carcinomas were identified. This study also showed no causal relationship or association between MUS and cancer or sarcoma. Moreover, it also demonstrates that based on the normal background rate and presence of malignancy in these populations, attempting to infer causation is assumptive and speculative.

Late exposure of TVT is uncommon, less than 1%, as is the need to reoperate. It is an unfortunate but a well-known complication of placement of midurethral slings and any permanent suture in the vagina. It is not emblematic of a defect in the suture or mesh, but the result of our body's immunological reaction to foreign bodies that is part of human's natural defense system. In some women there is a more marked inflammatory response resulting in delayed exposure of the mesh through the anterior vaginal wall. This is an uncommon but known complication of placement of any foreign body into the vagina that we knowingly consent patients about.

The long term tolerability, biocompatibility, durability, efficacy and safety of TVT has been well established in the human clinical data discussed in this report including numerous studies involving over 100,000 patients between 5 and 17 years duration, and these data refute the speculative theories espoused by Plaintiffs' experts. The design of the TVT has great utility in the surgical treatment of SUI.

Based on my own personal experience with these products, and my knowledge of the medical and clinical research, the midurethral approach is the best approach for surgically treating SUI and the use of products like TVT are safe, appropriate and effective. Any risks associated with placement of polypropylene slings are far outweighed by the benefits that are obtained from these products and the procedures.



Peter Sand, M.D.

Date: 7/22/18

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